REMARKS/ARGUMENTS

Claims 25 and 27-33 are pending. For convenience, the Examiner's rejections are addressed in the order presented in the September 22, 2003 Office Action.

I. Rejections under 35 U.S.C. §101

Claims 25 and 27-33 are rejected under 35 U.S.C. §101 because, allegedly, the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The Office Action allows that a reference submitted with the previous response, *i.e.*, Kato *et al.*, does provide a utility for the claimed Mkinase polynucleotide, *i.e.*, detection of genomic Mkinase mutations associated with cancer. But the Office Action also asserts that, because the specification does not disclose a particular chromosomal location for the genomic sequence, or a consequence of such a location, the claimed invention allegedly lacks utility.

The Office Action cites *In re Kirk*, 153 USPQ, 48, 53 (CCPA1967) for the proposition that disclosure of specific chromosomal localization and consequences are required in the specification to provide utility. However, *In re Kirk* is more properly cited as holding that disclosure of utilities such as having "biological activity" or "biological properties" do not meet the requirements of 35 U.S.C. §101. *Id.* at 52. The MPEP at 2107.01.III also cites *In re Kirk* for that proposition.

The application does not present a general assertion of the "biological activity" or "biological properties" of the claimed Mkinase nucleic acids. Instead, in the application Applicants assert a specific utility for diagnosis of and prognostic determination of cancer. Specific utility is defined by the MPEP as a utility that is specific to the subject matter claimed. The MPEP explains that applications show sufficient specific utility when applicants disclose a "specific biological activity" and reasonably correlate that activity to a "disease condition." MPEP §§2107.01 and 2107.02. Applicants assert that the disclosed specific use of Mkinase nucleic acids for diagnosing or determining prognosis of cancer meets the utility requirement of 35 U.S.C. §101. At no point does the MPEP or case law require a specific chromosomal

localization to support an assertion of diagnostic or prognostic use for a nucleic acid as asserted in the Office Action.

The specific "disease condition" asserted by applicants is cancer. The application defines a cell cycle associated disorder or disease state as a condition involving insufficient or excessive cell proliferation, and specifically identifies cancer as a cell cycle associated disorder or disease state. (Specification at page 40, lines 16-17.) The "specific biological activity" asserted by applicants is detection of Mkinase mutations associated with cancer for diagnosis or prognostic determination. The specification discloses determination of disorders based on mutated or variant cell cycle nucleic acids, *i.e.*, Mkinase nucleic acids. (Specification at page 40, line 32.) The specification also discloses determination of a difference Mkinase nucleic acid between a patient and a control as being indicative of a disease state or a propensity for a disease state (*i.e.*, cancer, as disease state is defined in the specification). (Specification at page 41, lines 10-12.) Kato *et al.*, the previously submitted reference, provides affirmation of these specific utilities by disclosing that the Mkinase genomic sequence maps to a breakpoint region associated with cancer. The specification also specifically asserts the use of Mkinase nucleic acids for mapping specific chromosomal regions and for the genetic analysis of individuals. (Specification at page 21, lines 4-9.)

The specification provides support for a reasonable correlation between Mkinase and cancer because the specification demonstrates specific interactions between Mkinase and Traf4 protein, which is known to have a role in cancer. (See, *e.g.* specification at page 5, lines 1-5.) In addition, the specification and a declaration filed with a previous response provide evidence that Mkinase has kinase activity and phosphorylates MAP kinase substrates. MAP kinases are known to be involved in carcinogenesis and apoptosis. (See, *e.g.*, specification at page 5, lines 13-21.)

Thus, the specification asserts at least one specific utility, detection of genomic Mkinase mutations associated with cancer, for the claimed Mkinase nucleic acids, *i.e.*, nucleic acids comprising the nucleotide sequence of SEQ ID NO:1 or encoding a protein comprising the amino acid sequence of SEQ ID NO:2. The Office Action has already admitted that this utility is

sufficient under 35 U.S.C. §101. (Office Action at page 4.) In view of the above arguments, Applicants respectfully request that the rejection under 35 U.S.C. §101 be withdrawn.

II. Rejections under 35 U.S.C. §112, first paragraph, enablement

Claims 25 and 27-33 are rejected under 35 U.S.C. §112, first paragraph as allegedly lacking enablement. Specifically, the Office Action alleges that the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, and that because of the alleged lack of utility, one of skill would not know how the use the claimed invention.

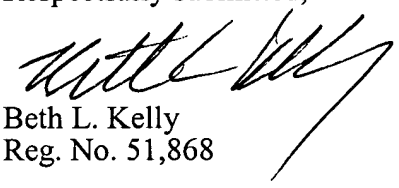
Applicants have submitted arguments in support of the Mkinase utility asserted in the application as filed in Section I of this response. In view of those arguments, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph also be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Beth L. Kelly
Reg. No. 51,868

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300
Attachments
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